IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Alexandria Division

ACTELION PHARMACEUTICALS LTD.,

Plaintiff,

v.

HON. MICHELLE K. LEE, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,

Defendant.

Civil Action No. 1:15-cv-1266

MEMORANDUM OPINION

This matter comes before the Court on a Motion to Stay filed by Defendant Michelle K. Lee, Director of the United States Patent and Trademark Office ("USPTO"). Dkt. No. 9. Defendant asks this Court to stay this case pending the decision of the U.S. Court of Appeals for the Federal Circuit in *Pfizer Inc. v. Lee*, No. 15-1265. *Pfizer* was argued before the Federal Circuit on November 2, 2015. Both cases involve the interpretation of the statute which provides for a patent term adjustment—the amount of time added to the life of a patent due to delays caused by the USPTO. Defendant argues this case should be stayed because the decision in *Pfizer* will govern the outcome in this case. Actelion opposes the Motion to Stay, arguing primarily that this case is factually distinct from *Pfizer* such that staying this case will not serve judicial economy.

I. Background

A. Statutory Framework[1]

The patent application process begins with an applicant filing a patent application with the USPTO. 35 U.S.C. § 111(a). The patent application undergoes a process of examination to determine whether the requirements for patentability have been met. *Id.* § 131. Often the first official action of the USPTO is the issuance of a restriction requirement. *Id.* § 132.

A restriction requirement is issued when a patent examiner determines that a patent application contains two or more independent and distinct inventions. *Id.* § 121. The restriction requirement divides the claims presented in the application into multiple groups. One group can be pursued in the application where the restriction requirement is made, while the other group(s) can be pursued by filing one or more divisional applications. *Id.*

A patent's enforceability begins on the issue date of the patent and ends twenty years from the patent application's effective filing date, which is the earliest filing date for which priority is claimed. 35 U.S.C. § 154(a)(2). Accordingly, when a divisional application results in a patent, its twenty year term is measured from the filing date of the parent patent application.

Because the examination process takes time, the enforceable lifetime of a patent is necessarily reduced by the amount of time it takes the USPTO to conduct the patent's examination. As such, Congress established patent term adjustments, or PTA, to compensate inventors for unreasonably long delays by the USPTO.

Prior to 1994, before adoption of the General Agreement on Tariffs and Trade, a patent term was seventeen years from the issue date. *Novartis AG v. Lee*, 740 F.3d 593, 595 (Fed. Cir. 2014). In 1994, Congress changed the effective term of a patent from seventeen years

[1] This section was largely taken from *Pfizer, Inc. v. Lee*, __ F. Supp. 3d __, 2014 WL 10212543 (E.D. Va. Nov. 6, 2014).

commencing from issuance to twenty years commencing from filing. *See* Uruguay Round Agreements Act, Pub.L. No. 103–465, § 532, 108 Stat. 4809, 4984 (1994). Under the seventeen-year regime, USPTO delays did not affect patent terms because a term commenced upon issuance rather than filing. Under the twenty-year regime, however, USPTO delays had the potential to consume the entirety of a patent's effective term. *See Wyeth v. Kappos*, 591 F.3d 1364, 1366 (Fed. Cir. 2010).

Most recently, in 1999, the American Inventors Protection Act ("AIPA") amended 35 U.S.C. § 154(b) to address this problem and protect patent terms from the effects of USPTO delay. "The new Act promised patent applicants a full patent term adjustment for any delay during prosecution caused by the PTO." *Wyeth*, 591 F.3d at 1366. Under the amended statute, the USPTO calculates patent term adjustments by considering three classes of USPTO delay: (i) an "A–Delay," which awards PTA for delays arising from the USPTO's failure to act by certain examination deadlines; (ii) a "B–Delay," which awards PTA for an application pendency exceeding three years; and (iii) a "C–Delay," which awards PTA for delays due to interferences, secrecy orders, and appeals. The USPTO calculates PTA by adding the A-, B-, and C–Delays, subtracting any overlapping days, and then subtracting any days attributable to applicant delay. *Wyeth*, 591 F.3d at 1367.

A–Delay is applicable to this case. The relevant portion of the PTA Statute describing A–Delay provides as follows:

> (A) Guarantee of prompt Patent and Trademark Office responses.--Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to—
>
> > (i) provide at least one of the notifications under section 132 or a notice of allowance under section 151 not later than 14 months after—
> >
> > > (I) the date on which an application was filed under section 111(a); or

> (II) the date of commencement of the national stage under section 371 in an international application;
>
> . . .
>
> the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

35 U.S.C. § 154(B)(1)(A).

If an applicant is dissatisfied with the USPTO's determination of PTA, the PTA Statute grants the applicant an opportunity to request reconsideration of the PTA determination. *Id.* § 154(b)(3)(B)(ii). If an applicant is still dissatisfied following the USPTO's reconsideration of PTA, the applicant "shall have exclusive remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration." *Id.* § 154(b)(4).

B. The Factual Background of the Complaint

On May 28, 2010, Eva Caroff, Kurt Hilpert, Francis Hubler, Emmanuel Meyer, and Dorte Renneberg ("the inventors") filed U.S. Patent Application 12/745,358 ("the '358 Application"). Compl., Dkt. No. 1, ¶ 8. This application was the "national stage entry" of International Patent Application PCT/IB2008/055002, filed on November 8, 2008. *Id.* ¶ 12. A few years later, on March 7, 2013, the inventors assigned all rights and interest in the patent application to Plaintiff Actelion. *Id.* ¶ 9. Thus, Actelion is the party with an interest in this case.

On March 14, 2012, the USPTO issued a first restriction requirement on the '358 Application. *Id.* ¶ 15. However, this restriction requirement was not proper because it "did not restrict all the different scopes in the claims but instead omitted certain claim scopes of interest

entirely." *Id.* ¶ 16. Actelion explained the deficiencies in the first restriction requirement to the patent examiner over the phone. *Id.* ¶ 17. The examiner agreed that the restriction requirement was deficient and issued a second restriction requirement on April 18, 2012. *Id.* ¶¶ 17-18. This second restriction requirement superseded and replaced the first restriction requirement "in its entirety." *Id.* ¶ 18. The second restriction requirement was also flawed and was superseded by a third restriction requirement issued on June 21, 2012. *Id.* ¶¶ 19-20.

On August 27, 2013, the USPTO granted the application and issued Patent No. 8,518,912 ("the '912 Patent"). *Id.* ¶ 25. The issue notification listed a Patent Term Adjustment of 314 days, which included a period of A-Delay of 229 days. *Id.* ¶¶ 25-26. As the national stage commencement date of the patent application was May 29, 2010,[2] the 14 month allowance prescribed by 35 U.S.C. § 154(b)(1)(A)(i)(II) expired on July 29, 2011. *Id.* ¶ 26. The 229 days of A-Delay was the length of time between July 29, 2011, and the issuance of the first restriction requirement on March 14, 2012. *Id.*

On October 28, 2013, Actelion filed a request for reconsideration of the Patent Term Adjustment. *Id.* ¶ 27. In response, the USPTO changed the PTA A-Delay from 226[3] days to 261 days, which is the time period between July 29, 2011, and the issuance of the second restriction requirement on April 18, 2012. *Id.* ¶ 30.

Actelion filed another request for reconsideration on December 3, 2014, asking that the PTA be extended to the date the third restriction requirement was filed. *Id.* ¶ 31. This calculation would result in an "A-Delay" of 325 days. *Id.* The USPTO rejected this request in a final decision issued on April 7, 2015. *Id.* ¶ 32. In its final decision, the USPTO characterized

[2] Although the application was filed on May 28, 2010, the PTA determination was made based on a national stage commencement date of May 29, 2010.
[3] The A-Delay was changed on September 29, 2014, to 226 days based on a revision of the national stage commencement date from May 29, 2010, to June 1, 2010.

its issuance of the second restriction requirement, which superseded the first restriction requirement, as "*sua sponte*." Pl. Ex. D, at 5. Actelion takes several issues with the USPTO's decision. First, Actelion insists that it brought the deficiencies in both the first and second restriction requirements to the patent examiner's attention. Second, Actelion argues that even if the second restriction requirement was *sua sponte*, the USPTO is unfairly and arbitrarily treating the issuance of the second and third restrictions differently based on whether the issuance is characterized as *sua sponte* or not. Accordingly, Actelion sought review of the agency's final decision in this Court.

C. Pfizer v. Lee

Defendant filed the current Motion to Stay on December 15, 2015. The Motion asks this Court to stay this case pending the outcome of *Pfizer v. Lee* which was argued before the Federal Circuit on November 2, 2015. *Pfizer* is an appeal of a decision issued by Judge Lee on November 6, 2014. 2014 WL 10212543 (E.D. Va. Nov. 6, 2014). In that case, Wyeth Holdings Corporation—a predecessor in interest to Pfizer—filed a patent application on May 2, 2003. *Id.* at *3. The 14 month statutory deadline for the USPTO to issue its first office action expired on July 2, 2004. *Id.* On August 10, 2005, 404 days after the deadline, the USPTO issued a restriction requirement. *Id.* at *4. During a documented telephonic interview, Wyeth explained to the patent examiner that the restriction requirement was defective because it omitted several claims. *Id.* The examiner agreed that it was flawed and issued a second restriction requirement on February 23, 2006—601 days after the July 2, 2004 deadline. *Id.* On October 11, 2011, the USPTO issued a Notice of Allowance.[4] *Id.* On April 10, 2012, the patent application was

[4] A notice of allowance notifies a patent applicant that the invention in his or her application is entitled to patent protection. *Janssen Pharmaceutica, N.V. v. Kappos*, 844 F. Supp. 2d 707, 709 (E.D. Va. 2012)

approved and the patent was issued, reflecting a PTA of 1291 days, which included 404 days of A-Delay. *Id.* This calculation of the A-Delay omitted the 197 days between the issuance of the first and second restriction requirements. *Id.* Pfizer, who obtained Wyeth in 2009, sought relief in the Eastern District of Virginia, asking the Court, among other things, to correct the PTA. Relying on *University of Massachusetts v. Kappos*, 903 F. Supp. 2d 77 (D.D.C. 2012), Judge Lee determined that Pfizer was not entitled to the additional 197 days of A-Delay because the "stoppage of the 'A-Delay' clock is not dependent on the ultimate accuracy of the office action" and because the USPTO "immediately provided a revised Restriction Requirement" after it was made aware of the flaws in the initial office action. *Id.* at *8-9.

II. Legal Standard

It is well settled that the decision to stay this action is entirely within the discretion of the Court. The authority to stay proceedings is incidental to the power in every court to manage the cases on its docket. *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). In deciding whether to grant a stay, a district court must weigh the competing interests of the effected parties. *Id.* There are three factors a district court should consider in this balancing test: "(1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; (3) potential prejudice to the non-moving party." *Buzzell v. JP Morgan Chase Bank*, 2015 WL 5254768, at *2 (E.D. Va. Sept. 9, 2015) (quotations and citations omitted). However, while the district court must weigh the interests of the parties, "[t]he party seeking a stay must justify it by clear and convincing circumstances outweighing potential harm to the party against whom it is

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The notice also "specifies the required issue fee, which must be paid within three months of issuance of the notice." *Id.* (citing 37 C.F.R. § 1.311). The USPTO will not issue the patent until the issue fee is timely paid. *Id.*

operative." *Id.* (quoting *Williford v. Armstrong World Indus., Inc.*, 715 F.2d 124, 127 (4th Cir.1983)).

III. Discussion

The Court will address each of the three relevant factors in turn.

A. Judicial Economy

Defendant argues that staying the case would serve the interests of judicial economy because the instant case is analogous to *Pfizer*. Both cases present the question of whether a defective restriction requirement stops the A-Delay clock. Because the cases present similar legal questions, Defendant insists that any decision by the Federal Circuit will either bind this Court or provide substantial guidance. In addition, Defendant insists that after the Federal Circuit's decision in *Pfizer* the USPTO may exercise its prerogative to remand and reconsider its determination of the PTA at issue in this case. It is true that the USPTO has the power to "seek a remand because of intervening events outside of the agency's control, for example, a new legal decision or the passage of new legislation." *SKF USA Inc. v. United States*, 254 F.3d 1022, 1028 (Fed. Cir. 2001) (citing *Lawrence v. Chater*, 516 U.S. 163, 169 (1996)). Because the USPTO may order reconsideration of its determination of the PTA of the '912 patent, Defendant argues it would waste judicial resources to move forward with this case now.

Actelion, in contrast, argues that this case should not be stayed because it is factually distinct from *Pfizer*. Actelion explains that in *Pfizer* the defects in the first restriction requirement issued by the USPTO were minor, such that Pfizer could still compose a response to it. In this case, Actelion explains, the first and second restriction requirements issued by the USPTO were so fundamentally flawed that Actelion could not fashion a response that was in

compliance with agency rules. Thus, Actelion asks this Court to move forward with this case to answer the question of whether a restriction requirement that is flawed to the point that a response is impossible stops the A-Delay clock. Because this precise question is not at issue in *Pfizer*, Actelion maintains that any outcome in *Pfizer* will not bind this Court in this case.

After reviewing the briefs filed in the Federal Circuit Court in *Pfizer*, the Court concludes that granting the stay serves the interest of judicial economy. The two cases are very similar and present almost identical legal questions. Plaintiff's attempt to distinguish the two invites the Court to split hairs. Because of their similarity, the Court agrees that the Federal Circuit's decision in *Pfizer* will likely bind or at least cabin this Court's future decisions in this case. Moreover, if this Court decided to deny the stay and allow the case to go forward, any decision rendered would likely have to be revisited after the Federal Circuit's decision *Pfizer*—an unnecessary duplication of judicial efforts. In addition, if the decision this Court reaches in this case were appealed to the Federal Circuit prior to a decision *Pfizer*, the Federal Circuit might be forced to consume judicial resources on this case while it also considers *Pfizer*—a sure waste of judicial resources. Because allowing this case to proceed immediately would impact this Court's and the Federal Circuit's resources, the Court concludes that this factor weighs in favor of granting the Motion to Stay.

B. Hardship Defendant Will Suffer if the Motion to Stay is Not Granted

Actelion argues that Defendant has failed to show any hardship that would justify a stay. Actelion points out that because the two cases involve different plaintiffs, different patents, and different factual circumstances, denying the stay would not result in duplicative litigation that would create repetitive and potentially inconsistent obligations for the Defendant. Further, the parties seem to agree that the present case will be decided purely on the judicial record, on cross-

dispositive motions, without the need for any additional discovery. While this may be true, the Government would be required to potentially duplicate the significant legal work that it has already done in the *Pfizer* case, in briefs to this Court, and possibly in briefs to the Federal Circuit. Because Government resources are limited, such repetition would needlessly burden the Defendant.

C. Potential Harm to Plaintiff if the Motion to Stay is Granted

Defendant argues there will be no harm to Actelion if the stay is granted. Defendant points out that any delay will be short considering that the Federal Circuit has already heard oral argument in *Pfizer* and is, presumably, currently drafting the opinion in that case. In addition, this short delay will surely not harm Actelion as the dispute here concerns whether the patent should be extended past its current expiration date in 2031—sixteen year from now. These arguments are persuasive and Actelion has made no attempt to explain how or why it will suffer harm if the stay is granted.

After reviewing all three factors, the Court finds granting the Motion to Stay is appropriate. Judicial economy, the most consequential factor in this case, weighs in favor of granting the stay. Granting the Motion will appropriately conserve the limited resources of the courts and the Government Defendant. The Court also finds it significant that, because of the timing of the two cases, Plaintiff will not suffer prejudice if the case is stayed pending a decision in *Pfizer*. The interest of judicial economy served by the stay thus clearly outweighs any potential harm to Actelion caused by the stay. *See Buzzell v. JP Morgan Chase Bank*, 2015 WL 5254768, at *2 (E.D. Va. Sept. 9, 2015).

III. Conclusion

For the foregoing reasons, it is hereby ORDERED that the Defendant's Motion to Stay (Dkt. No. 9) is GRANTED. An appropriate Order shall issue.

January 13 2016
Alexandria, VA

/s/
Liam O'Grady
United States District Judge